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REMARKS

Claims 68-81 are in this application. Claims 1-67 have been cancelled and replaced by claims 68-81.

In view of the new claims, the objections to the claims are moot.

Claim 67 has been cancelled so the rejection under 35 USC 101 is moot.

The rejection pursuant to 35 USC 112, second paragraph is moot in view of the new claims.

The examiner states that claims 1-33 are rejected on the basis of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-31 of US patent 5,858,371. The examiner has also rejected claims 1-67 as being obvious in view of 35 USC 103. These rejections are respectfully traversed.

Claims 1-67 are patentable in view of US patent 5,858,371. As shown and explained in the section Background of the Invention of this application (see page no. 4, line nos. 10-30; page no. 5, line nos. 1-20) the claimed invention is not obvious over the cited patent. The summary of the same is as follows:

a) Firstly, the presence of the phenolic compounds those are therapeutically useful for treatment of anorectal and colonic diseases due to their hemostatic and astringent properties, did not exist in the claimed extract of cited reference.

b) Secondly, it has been surprisingly found by the inventors of the present invention that the presence of the phenolic compounds like ellagic acid, gallic acid and tannins make the claimed extract more effective for treatment of hemorrhoids and other colonic diseases, as the phenolic compounds are known mucoprotective agents. The antimicrobial properties of these phenolic compounds further prevent secondary infections often accompanied with hemorrhoids, fissures, fistulas etc.

c) Thirdly, the amounts of the flavonoids apigenin-7-glycoside, and luteolin-7-glycoside in the composition claimed in this application are significantly less than the amounts included in the compositions claimed in US patent 5,858,371.

d) Further, the process of extraction claimed in the US patent 5858371 comprises an intermediate step of treating the concentrated extract with hot water (80-90°C), which resulted in the loss of especially the phenolic compounds from the extract, since they were washed out with the water. The process used in the preparation of extract in the present invention does not comprise this step. It was found that the water soluble portion contains a substantial amount of phenolic compounds, so instead washing a non-polar

solvent is used so that waxy materials and pigments are removed and there is no significant loss of phenolic compounds.

e) The composition claimed in the application has an improved pharmcological response in comparison to the composition disclosed in the cited reference.

f) Also, the extraction procedure of the disclosed *Euphorbia prostrata* extract I of the present invention is more cost effective and less time consuming in comparison to the procedure disclosed in the cited reference.

It is well known fact that the efficacy of a product in a certain disease conditions lies in the type and concentration of the active components. The concentration of active components in the extract claimed in the present application is substantially different from the concentration of active components in the extract claimed in US patent 5,858,371. The concentration of apigenin-7-glycoside in the patent is 30-45% by weight of the extract whereas the concentration of apigenin-7-glycoside in claim 1 of this application is 1-4% by weight of the extract. Moreover, the extract of the present invention also comprises phenolic compounds such as 1–15% by weight of ellagic acid, 1–12% by weight of gallic acid and 1–10% by weight of tannins, which has not been claimed in the cited reference. Also, cited reference discloses other components in the extract as an essential components i.e. 6-methoxy quercetin 3 glycoside, which is not a required component of the composition claimed in this application.

Further, evaluation of pharmacological activity of the extracts of both the inventions has been disclosed in their respective specifications. It has been disclosed in the column 13, line no. 13-26 of US patent 5,858,371 that assessment of pharmacological activity has been carried out in patients with complaints of hemorrhoids and fissures by using standardized extract, which is claimed in that patent. However, in the present invention antihaemorrhoidal activity studied by using *Euphorbia prostrata* extract specifically comprising apigenin-7-glucoside at a concentration of 1-4% weight alongwith phenolic compounds such as ellagic acid and gallic acid and the results show that this composition has a significant effect on lowering the anorectum: bodyweight ratio when compared to the control (carrageenan treated group) thus indicating antihaemorrhoidal activity.

Hence, the present invention is patentably distinct from the cited reference. Although both the inventions teach a pharmaceutical composition comprising an extract of *Euphorbia prostrata* for the treatment of anorectal or colonic diseases, the present invention is not obvious from the disclosure and claims of US patent 5,858,371, differs from the extract of the cited reference in terms of the extract composition; concentration of individual components and method of preparation of extract and treatment effect.

Thus it is respectfully requested that this rejection be withdrawn.

It is submitted that the application is in condition for allowance and favorable consideration is respectfully requested.

Respectfully submitted,

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